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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|----------------------------------|-------------|----------------------|-------------------------|-----------------|--|
| 09/890,306 | 10/25/2001 | Murali Nayudu | 13377-002001 | 8939 | |
| 7590 10/21/2005 | | | EXAMINER | | |
| Fish & Richard | dson | AFREMOVA, VERA | | | |
| 225 Franklin Str Boston, MA 0 | | ART UNIT | PAPER NUMBER | | |
| Doctor, Mile | | | 1651 | | |
| | | | DATE MAIL ED. 10/21/200 | • | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | | A | Application No. Applicant(s) | | | | | |
|--|--|---|--|--|---------|--|--|--|
| | | | 09/890,306 | NAYUDU ET AL. | | | | |
| | | E | xaminer | Art Unit | | | | |
| | | V | 'era Afremova | 1651 | | | | |
| Period fo | - The MAILING DATE of this communi r Reply | ication appea | rs on the cover sheet with | the correspondence a | ddress | | | |
| WHIC - Exten after 5 - If NO - Failur Any re | DRTENED STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE M. sions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this comm period for reply is specified above, the maximum state to reply within the set or extended period for reply eply received by the Office later than three months a d patent term adjustment. See 37 CFR 1.704(b). | AILING DAT of 37 CFR 1.136(a unication. atutory period will a will, by statute, cal | E OF THIS COMMUNICA i). In no event, however, may a reply pply and will expire SIX (6) MONTH use the application to become ABAN | TION. y be timely filed S from the mailing date of this DONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | | |
| 1) 又 | Responsive to communication(s) file | d on <i>15 Auai</i> | ıst 2005. | | | | | |
| •= | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | |
| / | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| • | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4)🖂 | ∑ Claim(s) <u>1-72,76-87,90-97 and 100-112</u> is/are pending in the application. | | | | | | | |
| | 4a) Of the above claim(s) <u>1-23 and 28-72</u> is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | | |
| 6) | Claim(s) is/are rejected. | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | |
| 8)⊠ | ∑ Claim(s) <u>24-27,76-87,90-97 and 100-112</u> are subject to restriction and/or election requirement. | | | | | | | |
| Application | on Papers | | | | | | | |
| 9)□ = | The specification is objected to by the | e Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| , | nder 35 U.S.C. § 119 | • | | | | | | |
| | - | for foreign pri | ority under 35 U.S.C. 8.1 | 19(a)-(d) or (f) | | | | |
| | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| - | , | documents h | ave been received | | | | | |
| | 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| | 3. Copies of the certified copies of the certi | | | | l Stogo | | | |
| | | | | ceiveu iii tiiis Nationa | Stage | | | |
| * 0 | application from the Internation | | ` '' | noived | | | | |
| 3 | ee the attached detailed Office action | i ioi a list oi i | the certified copies not re- | ceivea. | | | | |
| | • | | | | | | | |
| Attachment | (s) | | | | | | | |
| | of References Cited (PTO-892) | | 4) Interview Sum | | | | | |
| Paper No(s)/Mail Date | | | | | | | | |
| | nation Disclosure Statement(s) (PTO-1449 or No(s)/Mail Date | P10/SB/08) | 6) Other: | mai насені Арріісаціон (PT | O-102) | | | |
| • | | | | | | | | |

Application/Control Number: 09/890,306

Art Unit: 1651

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2005 has been entered.

Claims 73-75, 88, 89, 98 and 99 were canceled (8/15/2005).

Claims 1-24 and 28-72 were previously withdrawn from consideration as directed to nonelected inventions.

Claims 24-27,76-87,90-97,100-102 as amended and new claims 103-112 (filed 8/15/205) are under examination and subject to election of species requirement.

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) naturally-occurring mutant of *Pseudomonas* strain AN5 including particular strain AN5rif (AGAL Accession No. NM 00/09624); and

Art Unit: 1651

2) genetically engineered mutants of *Pseudomonas* strain AN5 including strains comprising tranposon, cosmid or multi-copy plasmid.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The instant pending claims, that are presently under examination, are deemed to correspond to the species listed above in the following manner:

- 1) Claims 25, 76, 90, 91, 100, 101, 103, 104, 107, 108, 111 and 112, drawn to a naturally-occurring mutant of *Pseudomonas* strain AN5 including particular strain AN5rif (AGAL Accession No. NM 00/09624); and
- 2) Claims 26, 27, 105, 106, 109 and 110, drawn to a genetically engineered mutant of *Pseudomonas* strain AN5 including strains comprising tranposon, cosmid or multi-copy plasmid.

The following claim(s) are presently generic: 24, 77-87, 92-97, 102 and 104.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

This application contains claims drawn to more than one of combinations of categories of inventions such as more than one product, process specially adapted for the manufacture of said product and process of using said product. In the instant case, claims are drawn to two products that are derived or made by two different specially adapted manufacturing processes such as a

Application/Control Number: 09/890,306

Art Unit: 1651

process for selection of spontaneous mutants and a targeted genetic engineering process. Thus, unity of inventions is lacking. See MPEP 1850. 37 CFR 1.475.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying outthe said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

Application/Control Number: 09/890,306 Page 5

Art Unit: 1651

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

October 18, 2005

VERA AFREMOVA

PRIMARY EXAMINER